DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2015

QUANTIMETRIX CORP.
KALYNA SNYLYK
2005 MANHATTAN BEACH BLVD.
REDONDO BEACH CA 90278-1205

Re: K142262
Trade/Device Name: AUTION CHECK Plus
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJW
Dated: March 09, 2015
Received: March 09, 2015

Dear Kalyna Snylyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142262

Device Name
AUTION CHECK Plus

Indications for Use *(Describe)*
The AUTION CHECK Plus is a quality control material intended for in vitro diagnostic use only, for performing quality control procedures with Arkray urine test strips and analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
AUTION CHECK Plus
(K142262)

Submitter:
Quantimetrix Corporation
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278

Contact person:
Kalyna Snylyk
Director Regulatory Affairs and Quality Assurance
Telephone: (310) 536-0006
Fax: (310) 536-9977

Date Summary prepared:
April 10th, 2015

Device identification:
Product Trade name:	AUTION CHECK Plus
Common name:	Urinalysis Controls, (Assayed)
Review Panel:	Clinical Chemistry and Clinical Toxicology Devices
Classifications:	Class I, reserved
Product code:	JJW
Regulation number:	21 CFR 862.1660

Device to which substantial equivalence is claimed

Dropper Urine Dipstick Control
Quantimetrix Corporation
Redondo Beach, CA 90278

510(k) number K874890

Description of Device

The AUTION CHECK Plus, is a two level liquid control prepared from human urine source material with added stabilizers and preservatives. Level 1 is positive for bilirubin and urobilinogen and Level 2 is positive for glucose, protein, blood, ketone, nitrite and leukocytes.

The urine donors are screened for HBs and HBc antigen , HCV, HIV1, and HIV2, and found to be negative by US FDA accepted methods. human source material used to manufacture this control was tested by FDA accepted methods

Value Assignment

The value assignment of each lot of AUTION CHECK Plus control is confirmed by laboratory analysis prior to release. Value assignment confirmation is performed by the Quality Control group in the laboratories of Quantimetrix Corporation. The testing is performed by three different operators using three different Arkray urinalysis analyzers. Each operator and analyzer performs a total of four tests on the control product. For each of the operators and analyzers, the mean of these four test results is then calculated. The means from all three operators and analyzers must fall within the specification range for the lot to be released.

Intended use

The AUTION™ CHECK Plus is a quality control material intended for in vitro diagnostic use only, for performing quality control procedures with Arkray urine test strips and analyzers.

Comparison of the new device with the Predicate Device

The new AUTION CHECK Plus claims substantial equivalence to the Dropper Urine Dipstick Control currently in commercial distribution (K874890). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Quantimetrix

Table 1: Similarities and Differences between new and predicate device:

Characteristics	AUTION CHECK Plus (New device)	Dropper Urine Dipstick Control (Predicate Device K874890)
Similarities		
Intended Use	Same	Is intended as a control for urinalysis reagent strips and analyzers.
Vial	Same	Twenty Five mL plastic squeezable bottle with dropper tip.
Kit	Same	Each kit contains package insert instructions and 4 x 25 mL Control bottles, 2 Level 1 and 2 Level 2.
Storage Condition	Same	Refrigerated (2-8°C)
Testing Procedure	Same	• Remove the control from the refrigerator and leave it the temperature of 18-25°C for at least 15 minutes • Mix by Inversion • Return to the refrigerator upon completion of testing
Form	Same	Liquid
Matrix	Same	Human Urine
Closed Vial Shelf Life	Same	At 2-8° C until the expiration date of 18 months

Differences		
Storage and Stability	**Open Vial Stability** Once opened, AUTION CHECK Plus can be used for 30 days as long as the unopened expiration date has not passed.	**Open Vial Stability** When stored at 2-8°C the opened Urine Dipstick Control bottles are stable until the expiration date stated on the label.
Testing Procedure	Dispensing of the Control Dispense the required volume of control into a sample tube. Wipe the tip of the control bottle and cap the bottle after dispensing.	Dispensing of the Control Remove cap and invert bottle. While holding dipstick, gently squeeze the sides of the dropper bottle, and touch the tip of the bottle to the dipstick. Draw across all of the reagent pads, thoroughly saturating each pad.
Analyte(s)	Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketone, Nitrite, Leukocytes, Specific Gravity	Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketone, Nitrite, Leukocytes, Specific Gravity, Albumin, Creatinine, hCG
Intended Use	Arkray does not make confirmatory tests so results are not included in the package insert.	Can be used as a control for confirmatory tests such as **Acetest,® Clinitest,®** and **Ictotest®** reagent tablets, and for **hCG** methods.

Statement of Supporting Data:

Accelerated stability studies were conducted to establish the open and unopened stability claims.
Accelerated stability studies were conducted to establish the shelf-life stability claim.
Acceptance criteria were met to support the product claims as follows:

Open vial Stability:	30 days at 2 to 8°C
Closed vial Stability:	18 months at 2 to 8°C
Shelf life Stability:	18 months at 2 to 8°C

Real time stability studies are ongoing and performed for every lot.

Conclusion:

Based on the performance characteristics indicated above, the Aution Check Plus is substantially equivalent to the predicate device Dropper Urine Dipstick Control, reference 510(k) K874890